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alfapump® DSR
RED DESERT interim results

Webcast presentation – 22 October 2020

Today's presenters

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Disclaimers

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Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see www.poseidonstudy.com.
- The DSR therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfa**pump® system in Europe.

COVID-19 disclaimer:

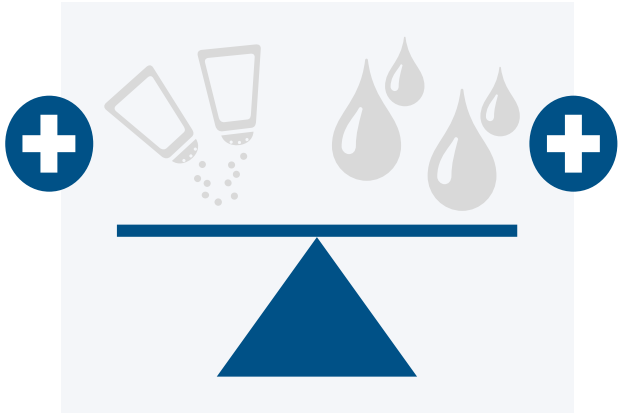
- Sequana Medical is closely following the evolution of the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt its operations as necessary.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, restrictions on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

RED DESERT: strong interim results

First five patients in alfapump® DSR repeated dose study

- ✓ Results indicate repeated dose **alfa**pump DSR therapy to be safe and effective in diuretic-resistant heart failure patients
- ✓ Results support DSR hypothesis: kidneys eliminate free water to maintain patients' serum sodium levels
- ✓ No patients required loop diuretic therapy during the six-week **alfa**pump DSR therapy period
- ✓ Following **alfa**pump DSR treatment, patients' response to near normal levels of diuretics was restored
- ✓ Durability of improvement in diuretic responsiveness; majority of patients had dramatic reduction in loop diuretic requirements lasting months post-DSR treatment

Fluid overload in heart failure – major clinical problem and key driver of healthcare costs



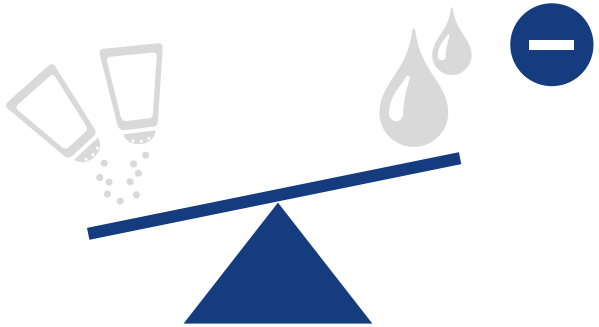
Excess sodium drives fluid overload

High unmet need to manage patients with residual congestion and keep them out of hospital

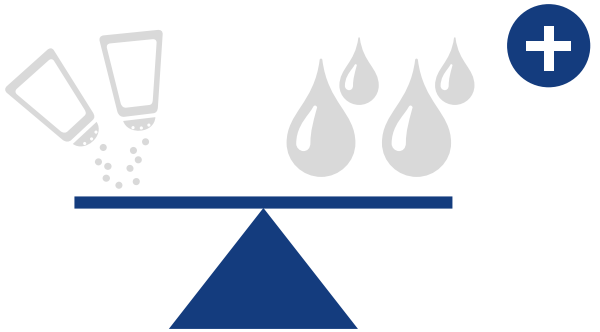
Sources: Costanzo et al., J. Am. Coll., 2007; Kilgore et al. (2017)
***HF**: Heart Failure*

Limitations of diuretic therapy in heart failure

Loop diuretics are the mainstay of therapy but have significant challenges in their use



Diuretics primarily remove hypotonic urine



Body retains water and cuts back on urination to restore homeostasis

- *40% of heart failure patients on IV loop diuretics have a poor response*
- *24% re-admission rate at 30 days*

Sources: Testani, Circ Heart Failure, 2014 & 2016; Ross et al. (2010)
***IV**: intravenous*

Direct Sodium Removal (DSR)

Sequana Medical's breakthrough approach to volume overload in heart failure

DSR therapy directly removes the sodium

Body eliminates excess fluid

"DSR represents a new potential therapy for non-renal sodium and fluid removal in edematous disorders such as heart failure"

Circulation

First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload

Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... **Show all Authors**

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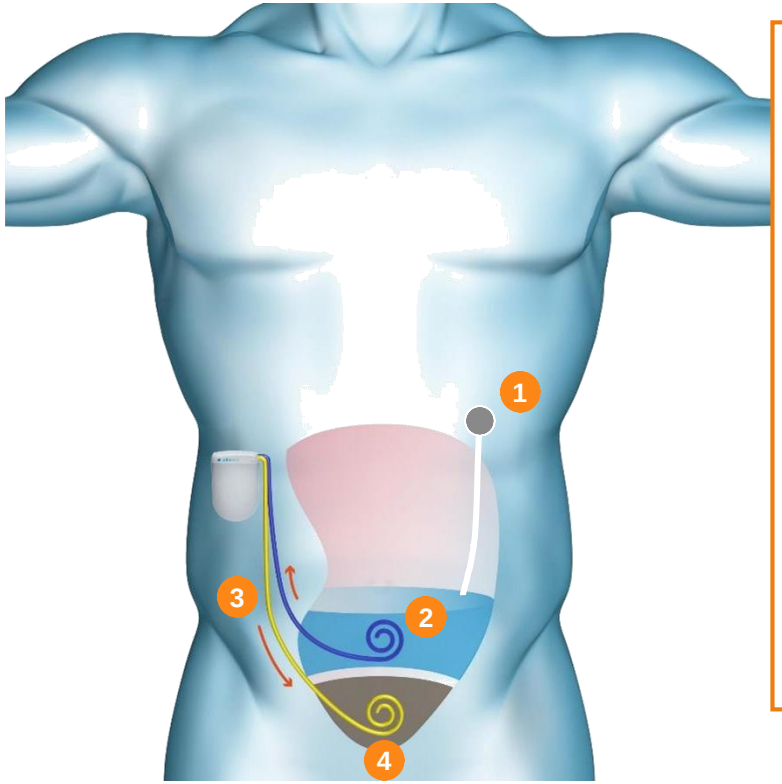
alfapump® DSR

Potential chronic therapy for heart failure patients with fluid overload that are not well controlled on diuretics

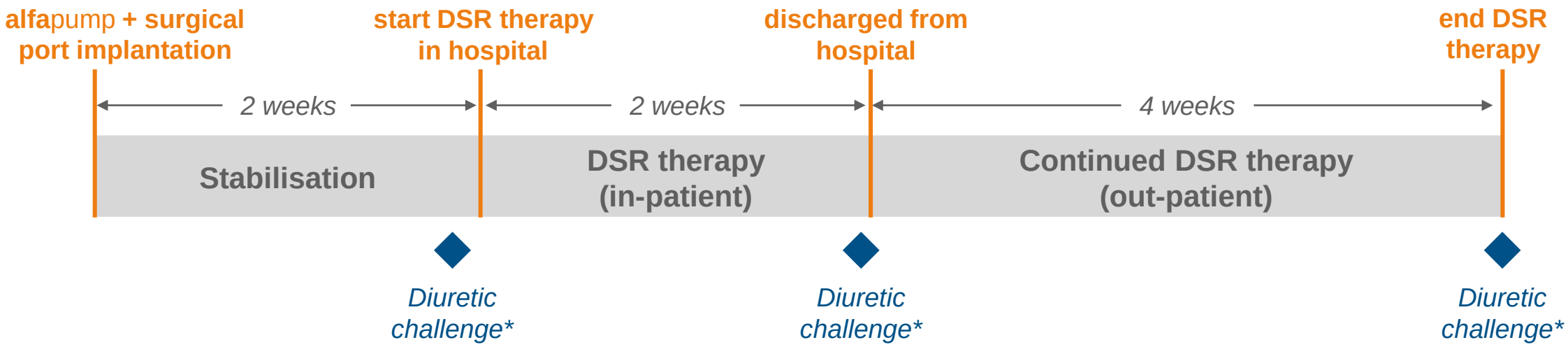


1. Administration of sodium-free DSR infusate to peritoneal cavity via implanted port
2. Sodium diffuses into DSR infusate
3. **alfa**pump pumps sodium-rich DSR infusate into the bladder
4. Body eliminates excess fluid through osmotic ultrafiltration and urination

Fundamental patents to reduce fluid overload in heart failure allowed in US and Europe

RED DESERT study design

Repeated dose proof-of-concept study of alfapump® DSR in up to 10 diuretic-resistant heart failure patients



Safety: absence/rate of device, procedure and/or therapy related serious adverse events

Feasibility: ability of the **alfa**pump DSR to maintain a neutral sodium balance and maintain euvolemia

Exploratory: impact of DSR to restore response to diuretics (diuretic challenge)

* intravenous dose of 40mg dose furosemide

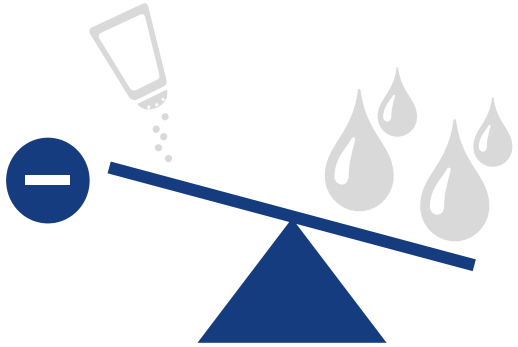
Heart failure patients on high dose diuretics

First five RED DESERT patients

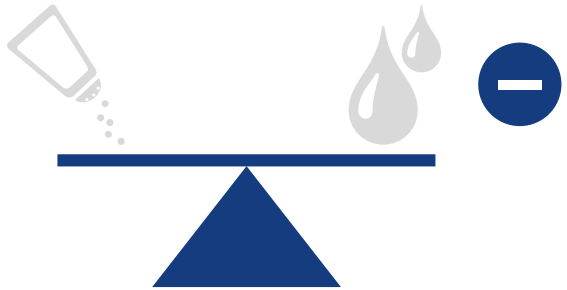
Mean values	
Left ventricular ejection fraction	mid 20%
NT-proBNP	2,500 – 3,000 pg/mL
Furosemide equivalent dose (standard of care)	150 – 200 mg/day

***NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide*

Interim data support DSR hypothesis



DSR therapy directly removes the sodium



Body eliminates excess fluid

- DSR removes the sodium and then the body responds to quickly and accurately eliminate the free water to maintain the sodium concentration in the blood
- No clinically significant changes in serum sodium levels / no progressive hyponatremia

Strong safety & efficacy results from first 5 patients

SAFETY

- Implant procedure of **alfa**pump® DSR and repeated dosing of DSR therapy were well-tolerated
- No clinically significant changes in serum sodium levels / no progressive hyponatremia
- Reported adverse events were manageable:
  - ⇨ catheter blockages due to pump settings (1 patient)
  - ⇨ site hematoma (1 patient)
  - ⇨ abdominal discomfort during operation of the pump (1 patient)

EFFICACY

- No diuretics required in any of the patients during 6-week **alfa**pump DSR treatment
- Reduced doses of DSR therapy and / or less frequent DSR dosing in majority of patients
  - ⇨ maintaining stable to lower weight and NT-proBNP compared to baseline

Restoring kidney response

Loop diuretic responsiveness restored to near normal levels in all 5 patients

- Diuretic response assessed by 6-hour excretion of fluid and sodium following IV administration of 40mg furosemide
  - ⇨ Baseline: objectively poor diuretic response
  - ⇨ End of 6-week study period: more than doubling of sodium excretion (near normal levels)

- Long-lasting diuretic responsiveness after completion of **alfa**pump® DSR therapy
  - ⇨ dramatic reduction in loop diuretics requirements in majority of patients

Based on these interim data, it appears that DSR therapy is not just an alternative means to remove sodium and water, it restores kidney response to near normal levels – opening up whole new ways it can be used

Developing our proprietary DSR infusate

- D10% was chosen as the initial DSR infusate for fastest proof-of-concept
- We are developing our proprietary next-generation DSR infusate:

✓ Improved therapeutic profile compared to D10%

✓ IP protected

✓ Recurring revenue from high gross margin consumable

⇨ studies ongoing at Yale University

⇨ pharmaceutical manufacturing development initiated

Clinical development strategy

Exciting impact on diuretic response requires additional investigation to support value of DSR therapy

RED DESERT

- Enrol up to five additional patients, with top-line data expected in H1 2021

SAHARA – dose-ranging study in decompensated heart failure patients

- Move into decompensated heart failure patients with residual congestion
- Dose ranging to learn more about improvement in diuretic response and durability of effect
- Key learnings to be taken into US controlled efficacy study
- D10% as DSR infusate

US efficacy study with proprietary DSR infusate

- Controlled efficacy study versus standard of care
- Treatment algorithm built upon learnings from SAHARA
- Paves the way and de-risks FDA pivotal study
- Creates a more valuable clinical and economic package for partnering

alfapump® DSR development strategy*

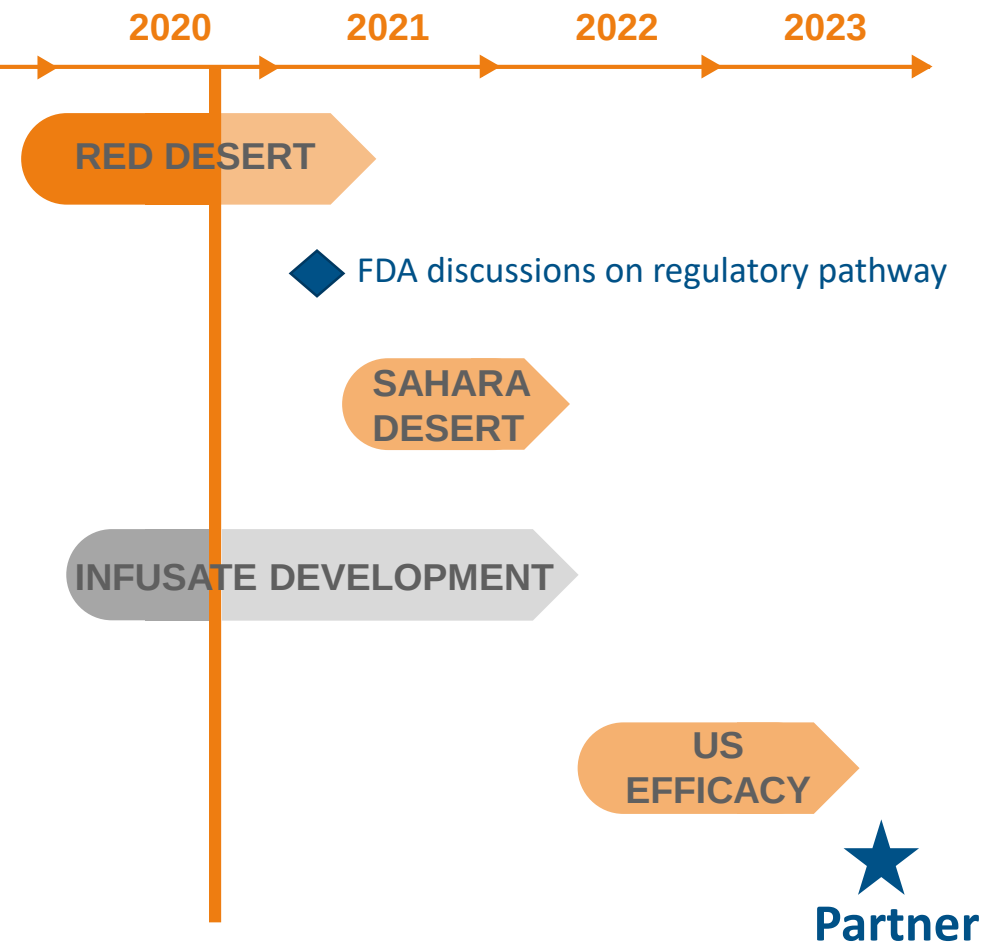
Study description

Proof-of-concept repeated dose **alfa**pump DSR study
D10% infusate; stable heart failure patients

alfapump DSR dose-ranging feasibility study**
D10% infusate; decompensated heart failure patients

Proprietary DSR infusate studies / manufacturing

alfapump DSR controlled efficacy study in US**
proprietary DSR infusate; decompensated heart failure patients

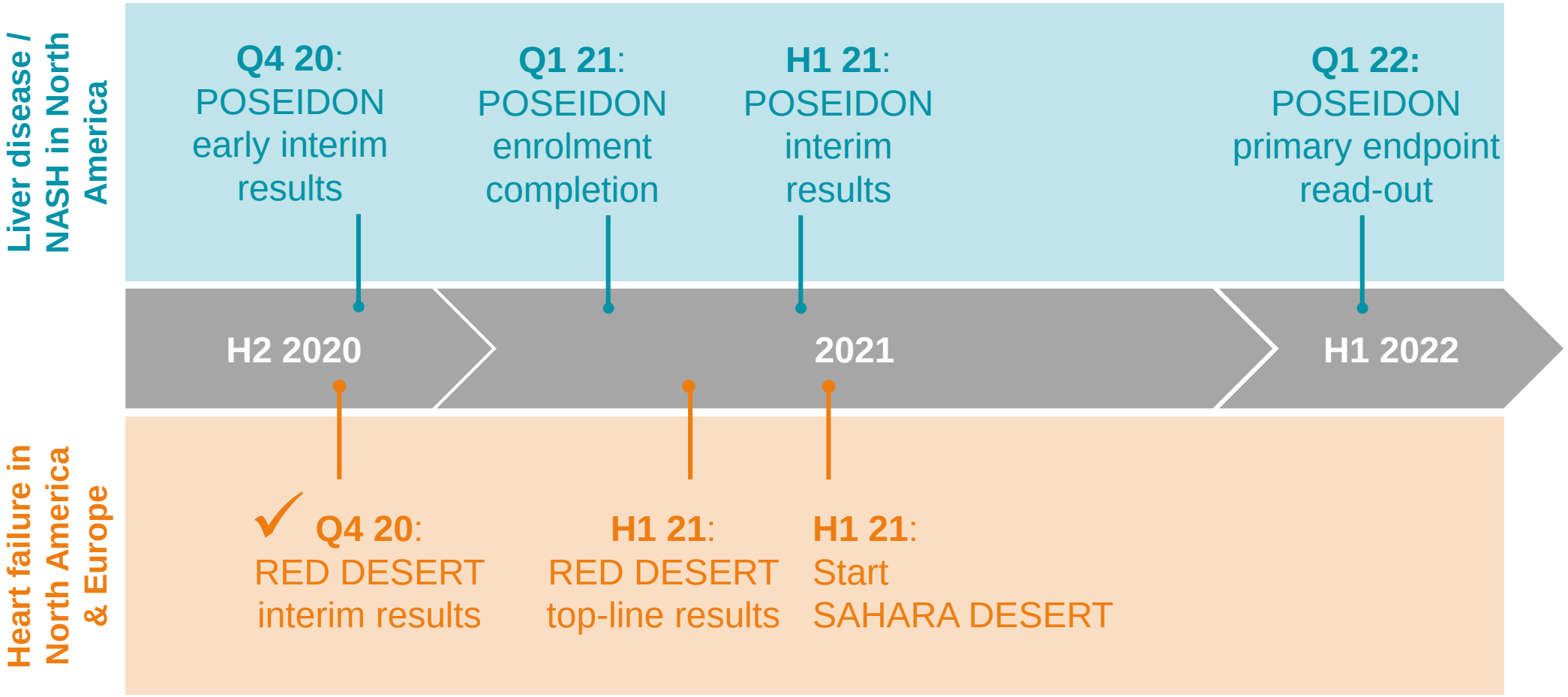


** Timelines subject to further developments related to the ongoing COVID-19 pandemic*
*** Subject to change and/or feedback from applicable regulatory authorities*

Business update

- Top-line data from all RED DESERT patients on track to report in H1 2021
- First feasibility study of **alfa**pump® DSR (SAHARA DESERT) planned to start in H1 2021
- Early interim data from POSEIDON study in recurrent and refractory liver ascites expected in Q4 2020
- European commercial supply of the **alfa**pump interrupted in Q4 2020; no impact on POSEIDON and RED DESERT studies

Expected Core Value Drivers & Outlook



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

Q&A